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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/670,847	09/24/2003	Siew Er	A03P1067	2331

36802 7590 11/09/2006

PACESETTER, INC.
15900 VALLEY VIEW COURT
SYLMAR, CA 91392-9221

EXAMINER	
FLORY, CHRISTOPHER A	

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 11/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/670,847	ER, SIEW	
	Examiner	Art Unit	
	Christopher A. Flory	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10 and 12-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10, 12-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 101

1. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-26 stand rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 1-15 are drawn to a method that does not produce a useful, concrete and tangible result, but rather are simply a series of steps that represent a process of thought that can be carried out by a care provider or other individual without the need of a tangible device. Claims 16-26 are drawn to an apparatus carrying out this method, but lack sufficient structural limitation to be considered a patentably useful, concrete and tangible invention (e.g. a means for recording information, means for analyzing the information, and means for presenting information can all refer to the care provider or other individual themselves).

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-10 and 12-26 stand rejected under 35 U.S.C. 102(b) as being anticipated by Mulligan et al. (US Patent 6,438,408).

Regarding claims 1-3, 9, 11, 12, 15, Mulligan et al. discloses a method of recording information related to procedures performed by a care provider during a follow-up consultation with a patient having an implanted device (Fig. 4; column 1, lines 15-22), analyzing the procedures; recommending one or more procedures for a subsequent follow-up consultation (column 9, lines 19-37; column 17, lines 12-42); and presenting information indicative of a recommended sequence of procedures for follow-up (column 16, lines 5-67).

Regarding claim 4, Mulligan et al. discloses the recording of threshold assessments (column 10, lines 26-48; column 24, lines 48-53).

Regarding claims 5 and 8, Mulligan et al. discloses recording rhythm assessments (column 17, lines 54-62; column 8, lines 36-61). This inherently involves pattern analysis, since a rhythm is a cyclically recurring pattern.

Regarding claim 6, statistical analysis is an inherent component of analyzing data whether performed by a computational device or a human user. Any device that records multiple data points and assesses these points to output a recommended procedure must inherently perform analysis, and therefore statistical analysis, of that data. Similarly, a human user who reads raw data points and comes to a conclusion based on those data points, has performed statistical analysis. (See also column 12, lines 44-67).

Regarding claim 7, a confidence level (or confidence interval) is synonymous with "margin of error" analysis, and can be defined as a range on either side of a mean or predetermined value for which a criterion is considered to be successfully met. For example, if event X is considered to occur at an average reading of 12V with a confidence interval of 1 volt, then a recording Y of 12.6V is read as a successful event X. Mulligan et al. discloses a method of recording parameters when the heart rate is in a normal range and stable within a certain stability tolerance programmed by the physician or determined over a series of heart cycles (column 17, line 64 through column 18, line 25). In the language of the example, event X is the normal heart rate, mean value is that value determined over a series of heart cycles and predetermined value is that programmed by the physician. The confidence interval is synonymous with the stability tolerance. Event Y is each calculated heart rate. This is a clear disclosure of confidence level analysis, and as such the instant application does not distinguish over the prior art.

Regarding claims 10, the method of Mulligan et al. inherently involves using guidelines, because guidelines are requisite for any meaningful analysis of data.

Regarding claim 13, it is inherent that a care provider have more than one patient with an implanted device, and further that the steps of the claimed method can be repeated for any number of patients by any number of care providers. Mere repetition of steps or methods is not enough to patentably distinguish over the prior art.

Regarding claim 14, it is inherent in the Malek et al. reference that the implanted device is manufactured by the same manufacturer because it is referring to the same device.

Regarding claim 16-26, Mulligan et al. shows a device (Fig. 2) with a means for recording procedures (column 6, lines 1-8; IMD memory); a means for analyzing the procedures (Fig. 2, microcomputer 102 and input signal processing circuit 108); statistical analysis software (column 12, lines 44-67); and a means for recommending one or more procedures (telemetry transceiver 124 and antenna 28); wherein recording procedures occur in real time (column 14, lines 24-52).

4. Claims 1-6, 9, 10, 12-22 and 24-25 stand rejected under 35 U.S.C. 102(b) as being clearly anticipated by Snell (US Patent 6,405,087, hereinafter Snell'087).

Snell'087 clearly discloses the method and apparatus of the instant application substantially as claimed in the ABSTRACT as well as Figures 1 and 2 and column 8, lines 16-30.

5. Claims 1-3, 5-6, 8-10, and 12-26 stand rejected under 35 U.S.C. 102(e) as being anticipated by Malek et al. (US Patent Publication 2003/0171789).

Regarding claims 1-3 and 11, Malek et al. discloses a method of recording information related to procedures performed by a care provider (physician) during a follow-up consultation with a patient having an implanted device, interrogating the implanted device for diagnostic data, analyzing the procedures, and recommending one or more procedures for a subsequent follow-up consultation (paragraphs [6] and [7],

[35], and [50]-[52]), wherein the one or more procedures inherently contains a sequence of steps or procedures.

It is noted that the screening phase is considered the first consultation such that the implant phase is the follow-up consultation. During the implant phase, the physician analyzes the data collected during the screening phase and adjusts parameters as needed to provide effective care to the patient, which is considered the recommending of procedures through physical reprogramming of the implanted device. It is further noted that the patient has a programmer that can be used to adjust the implanted device at their own discretion, and that the patient may also be considered a care provider.

Regarding claims 5 and 8, Malek et al. discloses a device that may be used for circadian rhythm linked therapies (paragraph [46]). This inherently involves pattern analysis, because the circadian rhythm is a cyclically recurring pattern of approximately 30 days.

Regarding claim 6, statistical analysis is an inherent component of analyzing data whether performed by a computational device or a human user. Any device that records multiple data points and assesses these points to output a recommended procedure must inherently perform analysis, and therefore statistical analysis, of that data. Similarly, a human user who reads raw data points and comes to a conclusion based on those data points, has performed statistical analysis.

Regarding claim 9, the method of Malek et al. involves comparing procedural information of the implant phase with the previously recorded procedural information of

the screening phase. Inherently, one cannot make a comparison without having a previously recorded set of data with which to compare a current set of data.

Regarding claims 10, the method of Malek et al. inherently involves using guidelines, because guidelines are requisite for any meaningful analysis of data.

Regarding claims 11, 12 and 15, the method of Malek et al. inherently involves presenting one or more procedures for the patient or care provider as discussed previously.

Regarding claim 13, it is inherent that a care provider have more than one patient with an implanted device, and further that the steps of the claimed method can be repeated for any number of patients by any number of care providers. Mere repetition of steps or methods is not enough to patentably distinguish over the prior art.

Regarding claim 14, it is inherent in the Malek et al. reference that the implanted device is manufactured by the same manufacturer because it is referring to the same device.

Regarding claim 16-22 and 24-25, Malek et al. discloses a device (Fig. 5C, physician programmer 310; Figure 6, patient programmer 320) with a means for recording procedures (memory 640); a means for analyzing the procedures (microcontroller 510 and microprocessor 620); and a means for recommending one or more procedures (telemetry unit 630 in figure 6; telemetry port, IR port, and input displays and buttons in Figure 5); further comprising a means for communicating with the implanted device (telemetry unit 620); wherein recording procedures occur in real time (Fig. 5, real time clock).

Regarding claims 23-26, the Malek et al. device is considered to perform statistical analysis based on the disclosure of monitoring circadian rhythm therapies (paragraph [46]). Any computational device that performs statistical analysis must inherently contain statistical analysis software in order for the system to function properly. Therefore, the instant application does not distinguish over the Malek et al. device.

Response to Arguments

6. Applicant's arguments filed 1 September have been fully considered but they are not persuasive.

7. Claims 1-10 and 12-26 stand rejected under 35 U.S.C. §101 for the reasons made of record and restated above in paragraph 1. Applicant argues that the claims produce useful, concrete and tangible results, in as much as they provide repeatable and practical information indicative of a recommended sequence of procedures for a follow-up consultation. Amendments to the claims notwithstanding, the method disclosed in claims 1-10 and 12-15 remains no more than a series of steps that can be carried out as a process of thought by a cognizant individual. The process does not require any outside input of information, nor does it require the aid of a tangible device in order to be practiced or repeated. The device as claimed lacks sufficient recitation of structure to be considered a tangible object or invention, as a means for recording, analyzing and presenting information can all still refer to the care provider or other

individual themselves rather than a device employed by any one of them. Therefore, the Examiner maintains the originally held rejection.

8. Claims 1-10 and 12-26 stand rejected under 35 U.S.C. §102(b) as being anticipated by Mulligan et al. for the reasons made of record and restated above in paragraph 3. Applicant argues that the Mulligan reference does not disclose presenting a recommended sequence of procedures for a subsequent follow-up consultation. However, Mulligan et al. clearly discloses several instances of sequential information or sequential steps to be undertaken. In column 16, lines 5-67, Mulligan et al. discloses that parameters are determined periodically throughout each day (i.e. sequentially). Additionally, in those same lines, Mulligan et al. discloses that the physician may advise the patient to undertake certain activities at precise times of the day or to initiate determination of parameters using a programmer. This is effectually an output from the physician, indicative to the patient, presenting information of a recommended sequence of procedures for a subsequent follow-up consultation. Therefore, the Examiner finds that the Mulligan et al. reference sufficiently discloses the limitations presented in the instant claims, and that the rejection under 35 U.S.C. §102(b) was appropriately made.

9. Claims 1-6, 9, 10, 12-22 and 24-25 stand rejected under 35 U.S.C. §102(b) as being anticipated by Snell'087 for the reasons made of record and restated above in paragraph 4. Applicant argues that Snell'087 does not disclose presenting a recommended sequence of procedures for a subsequent follow-up consultation. However, such a sequence of procedures is clearly disclosed in column 8, lines 16-30, which describes output of graded levels of concern, such as a notice and a warning.

This graded output advises personnel of conditions that require immediate attention or modification (i.e. outputs at the warning level) as well as conditions or events that require less immediate modification (i.e. outputs at the lower notice level). This is a clear disclosure of presenting information indicative of a recommended sequence of procedures for follow-up consultation, whereby warnings generated are treated before less imperative notices.

10. Claims 1-3, 5, 6, 8-10 and 12-26 stand rejected under 35 U.S.C. §102(b) as being anticipated by Malek et al. for the reasons made of record and restated above in paragraph 5. . Applicant argues that the Malek does not disclose presenting a recommended sequence of procedures for a subsequent follow-up consultation. However, any procedure, such as the one recommended in Malek et al. (paragraphs [6] and [7], [35], and [50]-[52]) inherently involves a sequence of steps to be undertaken. Therefore, even though Malek et al. does not explicitly cite a sequence of steps to be undertaken, it is inherently necessary to the procedure recommended, since a procedure must comprise steps of a particular sequence to be carried out as that specific procedure.

11. Applicant's arguments, see pages 9 and 10, filed 1 September 2006, with respect to the rejection of claim 16 under 35 U.S.C. §102(e) as anticipated by Gottlieb have been fully considered and are persuasive. The rejection of claim 16 has been withdrawn.

Conclusion

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher A. Flory whose telephone number is (571) 272-6820. The examiner can normally be reached on M - F 8:30 a.m. to 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher A. Flory

1 November 2006

George Manuel
Primary Examiner